

1615
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: John S. Patton et al.

Atty. Docket No.: 0005.15

Examiner: Gollamundi S. Kishore, Ph.D

Application No.: 10/612,376

Group Art Unit: 1615

Filed: 07/01/2003

Title: METHODS AND COMPOSITIONS
FOR THE PULMONARY DELIVERY
INSULIN

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, Virginia 22313-1450 on 08 NOV 04

Signed: Minnie Cotter

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56, §1.97 and §1.98

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

The references listed in the attached Forms PTO/SB/08A and B may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

The references on the attached Form PTO/SB/08A and B identified by an asterisk (*) were previously cited by or submitted to the PTO in a prior application relied upon for an earlier filing date.

11/15/2004 EAREGAY1 00000030 500340 10612376

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Attorney Docket No. 0005.15

Accordingly, in compliance with 37 CFR §§1.98 (d), copies of these references have not been provided.

This Information Disclosure Statement is being timely filed under 37 CFR §§1.97 and is being filed:

☐ within three months of the filing date of a national application or an RCE; within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or before the mailing date of a first Office action on the merits (whichever event occurs last);

☒ more than three months from the filing date of an application and after the mailing date of a first Office action on the merits, but before the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311 (whichever occurs first), and is accompanied by:

☒ the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under §1.97(c) (\$180.00)

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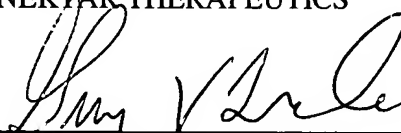
☒ If it is determined that any additional fees are due, the Commissioner is hereby authorized to charge such fees to Deposit Account 500348.

Respectfully submitted,

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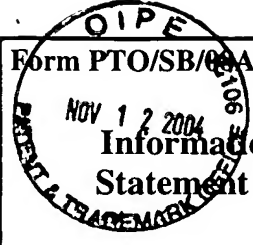
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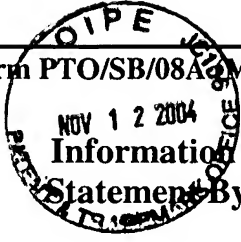
 Form PTO/SB/08A (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0005.15	Application No.: 10/612,376
	Applicant: John S. Patton et al.	
	Filing Date: 07/01/2003	Group: 1615

U.S. Patent Documents

Examiner Initial		Patent No.	Date	Patentee	Class	Sub-Class	Filing Date
	*	2,598,525	05/1952	Fox			
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	*	4,098,273	401/1978	Glenn			
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	*	4,294,829	10/1981	Suzuki et al.			

Examiner:	Date Considered:
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 Form PTO/SB/08A2 (Modified) Information Disclosure Statement By Applicant (Use Several Sheets if Necessary)	Atty Docket No.: 0005.15	Application No.: 10/612,376
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U.S. Patent Documents

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	*	4,338,931	07/1982	Cavazza			
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	*	4,830,858	05/1989	Payne et al.			

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Foreign Patent or Published Foreign Patent Application

Examiner Initial	No.	Document No.	Publication Date	Country or Patent Office	Class	Sub- class	Translation Yes No	
	*	902 257	08/1985	BE				
	*	18 12 574	06/1970	DE				
	*	24 15 159	10/1975	DE				
	*	31 41 498	04/1983	DE				
	*	01 61 072	09/1984	DE				
	*	0 015 123	09/1980	EP				
	*	0 072 046	02/1983	EP				
	*	0 111 216	06/1984	EP				
	*	0 122 036	10/1984	EP				
	*	0 140 489	05/1985	EP				
	*	0 193 372	09/1986	EP				
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	*	0 237 507	09/1987	EP				
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	*	0 347 779	12/1989	EP				
	*	0 360 340	03/1990	EP				
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Examiner Initial	No.	Document No.	Publication Date	Country or Patent Office	Class	Sub- class	Translation Yes No	
	*	1 527 605	10/1978	GB				
	*	2 105 189	03/1983	GB				
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	*	62267238	11/1987	JP				
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	*	0628930	09/1978	RU				
	*	1003926	03/1983	RU				
	*	0883174	11/1981	RU				
	*	84/00294	02/1984	WO				
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	*	88/04556	06/1988	WO				
	*	88/09163	12/1988	WO				
	*	90/04962	05/1990	WO				
	*	90/05182	05/1990	WO				
	*	90/07351	07/1990	WO				
	*	90/09780	09/1990	WO				
	*	90/15635	12/1990	WO				
	*	91/02545	03/1991	WO				
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	*	91/06282	05/1991	WO				
	*	91/16038	10/1991	WO				
	*	91/16882	11/1991	WO				
	*	92/10229	06/1992	WO				
	*	93/00951	01/1993	WO				

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Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	*	ANDREWS, "Gelatin Capsules Revamped for New Generation of Pills," New York Times, Saturday, September 16, 1992, 19(N), 35(L), col. 5, 9 col. in.
	*	ANNEAR, "Observations on Drying Bacteria from the Frozen and from the Liquid State," Austral. J. Exp. Biol. (1958), 36:211-221.
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	*	BRUNI ET AL., "Glass Transitions in Soybean Seed, Relevance to Anhydrous Biology," Plant Physiol. (1991), 96:660-663.
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Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	*	COLTHROPE ET AL., "The Pharmacokinetics of Pulmonary-Derived Insulin: A Comparison of Intratracheal and Aerosol Administration to the Rabbit," Pharm. Res. (1992), <u>9</u> (6):764-768.
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	*	CROWE ET AL., "Are Freezing and Dehydration Similar Stress Vectors? A Comparison of Modes of Interaction of Stabilizing Solutes with Biomolecules," Cryobiology (1990), <u>27</u> :219-231.
	*	DUCHATEAU, "Bile Salts and Intranasal Drug Absorption," International J. of Pharmaceutics (1986), <u>31</u> :193-199.
	*	DOLOVICH, "Lung Dose, Distribution, and Clinical Response to Therapeutic Aerosols," Aerosol Sci. and Tech. (1993), <u>18</u> :230-240.
	*	ELLIOT ET AL., "Parental Absorption of Insulin for the Lung in Diabetic Children," Aust. Paediatr. J. (1987), <u>23</u> :293-297.
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	*	GÄNSSLEN, "Über Inhalation Von Insulin" Klin. Wochenschr. January 1925, <u>4</u> :71, (with translation).
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Other Documents

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	*	GREEN ET AL., "Phase Relations and Vittrification in Saccharide-Water Solutions and The Trehalose Anomaly," J. Phys. Chem. (1989), <u>93</u> :2880-2882.
	*	HABENER, "Parathyroid Hormone: Secretion and Metabolism In Vivo," Proc. Nat. Acad. Sci., USA, Dec. 1971, <u>68</u> (12):2986-2991.
	*	HASTINGS ET AL., Clearance of Different-Sized Proteins from the Alveolar Space in Humans and Rabbits" J. Appl. Physiol. (1992), <u>73</u> :1310-1316.
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	*	HESCH, "Pulsatile Secretion of Parathyroid Hormone and Its Action on a Type I and Type II PTH Receptor: A Hypothesis for Understanding Osteoporosis," Calcified Tissue Int. (1988), <u>42</u> :341-344.
	*	HUBBARD ET AL., "Strategies for Aerosol Therapy of α_1 -Antitrypsin Deficiency by the Aerosol Route," Lung, 1990, <u>168</u> , Supplement 1990, Proceedings of the 8 th Congress of SEP, Edited by H. Matthys, pp. 565-578.
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